IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :

Katsushi TOKUNAGA et al. : Docket No. 2000_1639A

Serial No. 09/725,752 :

Filed November 30, 2000 :

REAGENT FOR DIAGNOSIS OF CROHN'S DISEASE

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of [X] the references listed on attached form PTO-1449 and/or [] the additional information identified below in paragraph 3. A legible copy of each reference listed on the form PTO-1449 and each U.S. patent application listed below is enclosed, except a copy is not provided for each reference previously cited by or submitted to the Patent Office in prior parent application Serial No. .

1a. [X] This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, **or**

before the mailing date of the first Office Action on the merits,

and thus no certification and/or fee is required.

1b. [] This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

(1) [] the certification of paragraph 2 below is provided, **or**

(2) [] the fee of $180.00 specified in 37 CFR 1.17(p) is enclosed.

1c. [] This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

the certification of paragraph 2 below is provided, and

the fee of $180.00 specified in 37 CFR 1.17(p) is enclosed.

2. It is hereby certified

a. [] that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or

b. [] that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. [X] Consideration of the following additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

The present invention is based on the report published by the inventors in an academic meeting held in Japan on December 2, 1999, i.e. within one year before the filing date of this application. The enclosed document AG and a copy and its English translation of the portion of the abstract relating to the report. The document AN is a report (poster) presented in the

academic meeting. The abstract was published then, and therefore, needs to be submitted to the U.S. PTO in an IDS. As to the poster used in the meeting, it is uncertain if this document is considered a printed "publication" under 35 USC 102(b) so as to require it to be disclosed in an IDS. As a precaution, the content of the poster is disclosed to read as follows:

We detected glucocorticoid receptor alpha, cytochrome oxidase subunit 1, cytochrome b, 17 hydroxysteroid dehydrogenase, Fos, PPAR alpha, type 6 protein phosphatase regulated by IL-2 (6PP regulated by IL-2), short form FLICE inhibitory protein ($FLIP_s$), long form FLIP ($FLIP_L$), Traf2 and Nck interacting kinase (TNIK) as the genes that over-expressed in the inflamed intestinal tissue than in the non-inflamed intestinal tissue, by the Differential Display method.

The over-expression of 6PP regulated by IL-2 suggests proliferation of T cell by IL-2, that of TNIK suggests activated state of the TNFR1-TRADD-Traf2-TNIK-JNK pathway, and that of FLIP suggests the presence of apoptosis-resistant cell in the lesion.

Consideration is respectfully solicited.

4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:

a. [] a full or partial English language translation submitted herewith,

b. [] a foreign patent office search report (in the English language) submitted herewith,

c. [] the concise explanation contained in the specification of the present application at page,

d. [] the concise explanation set forth in the attached English language abstract,

e. [] the concise explanation set forth below or on a separate sheet attached to the reference:

5. [ ] A foreign patent office search report citing one or more of the references is enclosed.

Respectfully submitted,

Katsushi TOKUNAGA et al.

By _____
Warren M. Cheek, Jr.
Registration No. 33,367
Attorney for Applicants

WMC/dlk
Washington, D.C.
Telephone (202) 721-8200
February 28, 2001

Sheet 1 of 1

FORM PTO 1449 (*modified*)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

LIST OF REFERENCES CITED BY APPLICANT(S)
(*Use several sheets if necessary*)

Date Submitted to PTO: February 28, 2001

ATTY DOCKET NO.	SERIAL NO.
2000_1639A	09/725,752

APPLICANT
Katsushi TOKUNAGA et al.

FILING DATE	GROUP
November 30, 2000	

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
	AB							
	AC							
	AD							
	AE							
	AF							

OTHER DOCUMENT(S) *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	AG	K. Hagiwara et al., "Identification of genes expressed in the intestinal lesions of Crohn disease by differentiation display method", Proceedings of the Japanese Society for Immunology, Vol. 29, 1999, p. 176 and its English translation thereof.
	AH	M. Filali et al., "Identification of a Type 6 Protein Ser/Thr Phosphatase Regulated by Interleukini-2 Stimulation", Journal of Cellular Biochemistry, Vol. 73, No. 2, 1999, pp. 153-163.
	AI	C. Alan Fu et al., "TNIK, a Novel Member of the Germinal Center Kinase Family that Activates the c-Jun N-terminal Kinase Pathway and Regulates the Cytoskeleton", The Journal of Biological Chemistry, Vol. 274, No. 43, October 22, 1999, pp. 30729-30737.
	AJ	M. Irmler et al., "Inhibition of Death Receptor Signals by Cellular FLIP", Nature, Vol. 388, July 10, 1997, pp. 190-195.
	AK	S. Hollenberg et al., "Primary Structure and Expression of a Functional Human Glucocorticoid Receptor cDNA", Nature, Vol. 318, December 1985, pp. 635-641.
	AL	F. Sanger et al., "Cloning in Single-Stranded Bacteriophage as an Aid to Rapid DNA Sequencing", J. Mol. Biol. Vol. 143, 1980, pp. 161-178.
	AM	S. Anderson et al., "Sequence and Organization of the Human Mitochondrial Genome", Nature, Vol. 290, April 9, 1981, pp. 457-465.
	AN	Report presented in the 29th Annual Meeting of the Japanese Society for Immunology 1999.

EXAMINER	DATE CONSIDERED

**EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.*